

AMENDMENTS TO THE CLAIMS

Please amend the claims as follows.

Claim 1 (original): A pharmaceutical formulation comprising one or

5 more excipients and $3\alpha, 16\alpha, 17\beta$ -trihydroxy- 5α -androstane, $3\alpha, 16\alpha$ -
dihydroxy-17-oxo- 5α -androstane, $3\beta, 16\alpha, 17\beta$ -trihydroxy- 5α -androstane,
 $3\beta, 16\alpha$ -dihydroxy-17-oxo- 5α -androstane, $3\alpha, 16\beta, 17\beta$ -trihydroxy- 5α -
androstane, $3\alpha, 16\beta$ -dihydroxy-17-oxo- 5α -androstane, $3\beta, 16\beta$ -dihydroxy-17-
oxo- 5α -androstane, $3\alpha, 16\alpha, 17\beta$ -trihydroxy- 5β -androstane, $3\alpha, 16\alpha$ -dihydroxy-
10 17-oxo- 5β -androstane, $3\beta, 16\alpha, 17\beta$ -trihydroxy- 5β -androstane, $3\beta, 16\alpha$ -
dihydroxy-17-oxo- 5β -androstane, $3\alpha, 16\beta, 17\beta$ -trihydroxy- 5β -androstane,
 $3\alpha, 16\beta$ -dihydroxy-17-oxo- 5β -androstane, $3\beta, 16\beta$ -dihydroxy-17-oxo- 5β -
androstane or a 2-oxa, 11-oxa or 19-nor analog of any of these compounds.

15 Claim 2 (original): The pharmaceutical formulation of claim 1 wherein
the compound is $3\alpha, 16\alpha, 17\beta$ -trihydroxy- 5α -androstane.

Claim 3 (original): The pharmaceutical formulation of claim 1 wherein
the compound is $3\alpha, 16\alpha$ -dihydroxy-17-oxo- 5α -androstane.

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Claim 4 (original): A pharmaceutical formulation for buccal or
sublingual administration comprising one or more excipients and a compound
wherein the compound is 16α -fluoro-17-oxoandrost-5-ene, 3α -hydroxy- 16α -
fluoro-17-oxoandrost-5-ene, 3β -hydroxy- 16α -fluoro-17-oxoandrost-5-ene 7α -
25 hydroxy- 16α -fluoro-17-oxoandrost-5-ene, 7β -hydroxy- 16α -fluoro-17-
oxoandrost-5-ene, 16α -fluoro-7,17-dioxoandrost-5-ene.

Claim 5 (original): The pharmaceutical formulation of claim 4 wherein
the compound is micronized.

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Claim 6 (original): The pharmaceutical formulation of claim 4 wherein the compound is 16 α -fluoro-17-oxoandrost-5-ene.

Claim 7 (original): A pharmaceutical formulation comprising one or
5 more excipients and two or more of 3 β -hydroxy-16 α -bromo-17-oxo-5 α -androstane, 3 β -hydroxy-16 β -bromo-17-oxo-5 α -androstane and 3 β -hydroxy-16 α -bromo-17-oxo-5 α -androstane hemihydrate.

Claim 8 (original): The pharmaceutical formulation of claim 7 wherein
10 the pharmaceutical formulation is for oral, buccal, sublingual or aerosol administration.

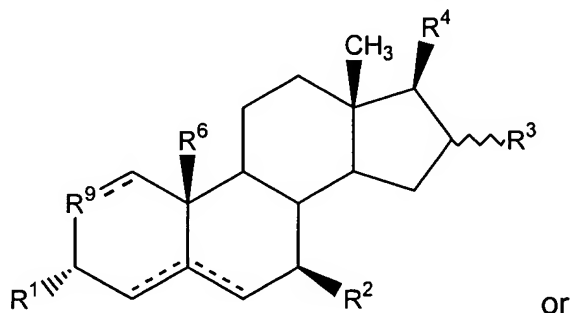
Claim 9 (original): The pharmaceutical formulation of claim 7 comprising 7 3 β -hydroxy-16 β -bromo-17-oxo-5 α -androstane and 3 β -hydroxy-16 α -bromo-17-oxo-5 α -androstane hemihydrate.
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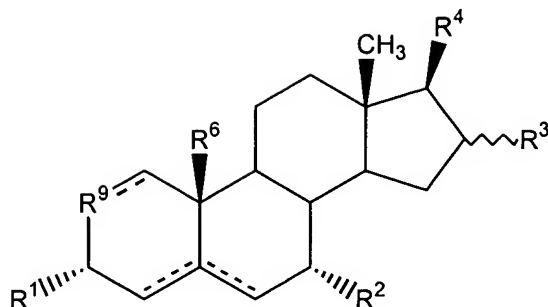
Claim 10 (original): The pharmaceutical formulation of claim 9 wherein the pharmaceutical formulation is for oral, buccal, sublingual or aerosol administration.

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Claims 11-22 (canceled)

Claim 23 (new): A method to treat or prevent osteoporosis or a bone fracture in a subject in need thereof, comprising administering to the subject
25 an effective amount of a compound having the structure





wherein,

R¹ is -OR^{PR}, -SR^{PR}, -N(R^{PR})₂, -N₃, -NO₂, an ester, a thioester, a phosphoester, a phosphothioester, a sulfate ester, an amino acid, a peptide, an ether, a thioether, a carbonate, a carbamate, an optionally substituted monosaccharide or an optionally substituted oligosaccharide;

R² and R³ independently are -H, -OR^{PR}, =O, -SR^{PR}, =S, -N(R^{PR})₂, -N₃, =NOH, -CN, -NO₂, an amino acid, a peptide, an ether, a thioether, an acyl group, a thioacyl group, a carbonate, a carbamate, a thioacetal, a halogen, an optionally substituted alkyl group, an optionally substituted alkenyl group, an optionally substituted alkynyl group;

R⁴ is -OR^{PR}, =O, -SR^{PR}, =S, -N(R^{PR})₂, -N₃, =NOH, -NO₂, an ester, a thioester, a phosphoester, a phosphothioester, a phosphonoester, a phosphiniester, a sulfate ester, an amino acid, a peptide, an ether, a thioether, an optionally substituted heteroaryl moiety, an optionally substituted monosaccharide or an optionally substituted oligosaccharide;

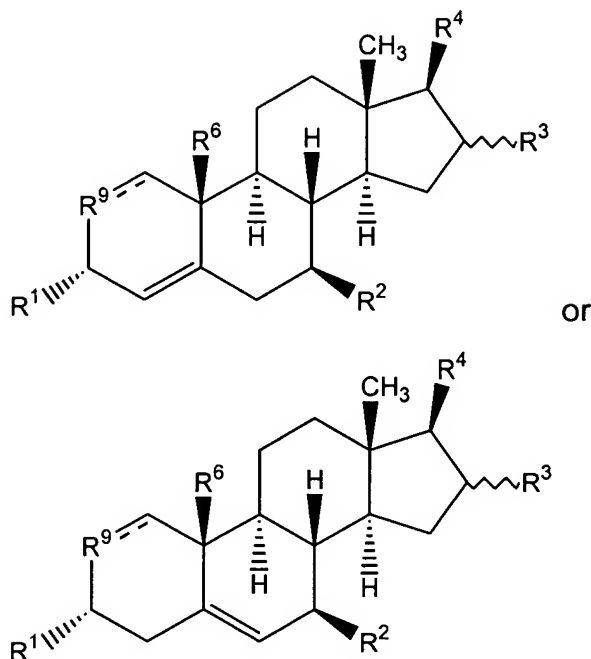
R⁶ is -H or optionally substituted alkyl;

R⁹ is -CHR¹⁰-, -O-, -S-, -NR^{PR}-, or R⁹ is absent, leaving a 5-membered ring, wherein R¹⁰ is -OH, -SH, halogen or optionally substituted alkyl;

R¹³ independently is C₁₋₆ alkyl;

R^{PR} independently are -H or a protecting group.

Claim 24 (new): The method of claim 23 wherein the compound has the structure



Claim 25 (new): The method of claim 24 wherein

- 5 (1) R^1 and R^4 are -OH, R^2 and R^3 are -H and R^9 is -CH₂- or -CH=;
- (2) R^1 and R^4 are -OH, R^2 is -H, R^3 is -Br and R^9 is -CH₂- or -CH=;
- (3) R^1 and R^4 are -OH, R^2 is -H, R^3 is -F and R^9 is -CH₂- or -CH=;
- (4) R^1 , R^2 and R^4 are -OH, R^3 is -H and R^9 is -CH₂- or -CH=;
- (5) R^1 , R^2 and R^4 are -OH, R^3 is -Br and R^9 is -CH₂- or -CH=;
- 10 (6) R^1 , R^2 and R^4 are -OH, R^3 is -F and R^9 is -CH₂- or -CH=;
- (7) R^1 , R^3 and R^4 are -OH, R^2 is -H and R^9 is -CH₂- or -CH=;
- (8) R^1 , R^2 , R^3 and R^4 are -OH and R^9 is -CH₂- or -CH=;
- (9) R^1 and R^4 independently are -OR^{PR}, -SR^{PR}, -N(R^{PR})₂, an ester, a thioester, a phosphoester, a monosaccharide, an oligosaccharide, a carbonate or a carbamate, R^2 and R^3 are -H and R^9 is -CH₂- or -CH=;
- 15 (10) R^1 and R^4 independently are -OR^{PR}, -SR^{PR}, -N(R^{PR})₂, an ester, a thioester, a phosphoester, a monosaccharide, an oligosaccharide, a carbonate or a carbamate, R^2 is -H, R^3 is -Br and R^9 is -CH₂- or -CH=;
- (11) R^1 and R^4 independently are -OR^{PR}, -SR^{PR}, -N(R^{PR})₂, an ester, a thioester, a phosphoester, a monosaccharide, an oligosaccharide, a carbonate or a carbamate, R^2 is -H, R^3 is -F and R^9 is -CH₂- or -CH=;
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(12) R^1 and R^4 independently are $-OR^{PR}$, $-SR^{PR}$, $-N(R^{PR})_2$, an ester, a thioester, a phosphoester, a monosaccharide, an oligosaccharide, a carbonate or a carbamate, R^2 is $-H$, R^3 is $-OH$ and R^9 is $-CH_2-$ or $-CH=$;

5 (13) R^1 and R^4 independently are $-OR^{PR}$, $-SR^{PR}$, $-N(R^{PR})_2$, an ester, a thioester, a phosphoester, a monosaccharide, an oligosaccharide, a carbonate or a carbamate, R^2 and R^3 are $-OH$ and R^9 is $-CH_2-$ or $-CH=$;

10 (14) R^1 and R^4 independently are $-OR^{PR}$, $-SR^{PR}$, $-N(R^{PR})_2$, an ester, a thioester, a phosphoester, a monosaccharide, an oligosaccharide, a carbonate or a carbamate, R^2 is $-OH$, R^3 is $-H$, $-F$, $-Cl$ or $-Br$ and R^9 is $-CH_2-$ or $-CH=$;

(15) R^1 is $-H$, R^2 is $-OH$ or $=O$, R^3 is $-OH$, $-F$, $-Cl$ or $-Br$, R^4 is $-OR^{PR}$, $-SR^{PR}$, $-N(R^{PR})_2$, an ester, a thioester, a phosphoester, a monosaccharide, an oligosaccharide, a carbonate or a carbamate and R^9 is $-CH_2-$ or $-CH=$;

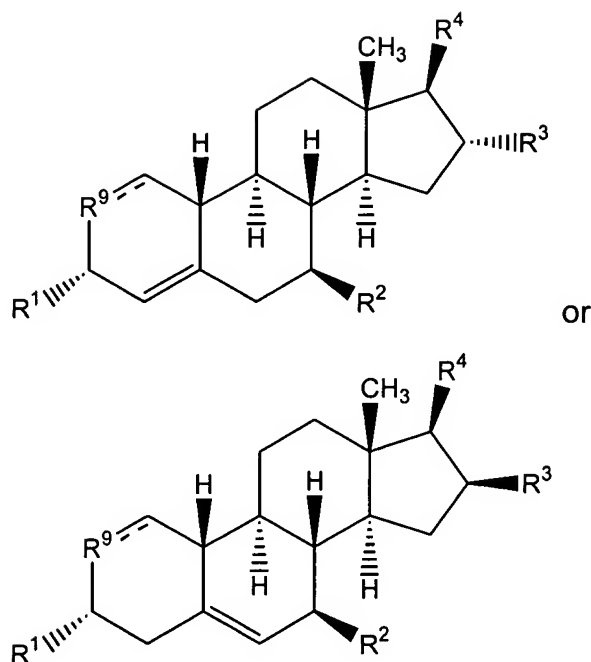
15 (16) R^1 and R^2 are $-H$, R^3 is $-OH$ or $=O$, $-F$, $-Cl$ or $-Br$, R^4 is $-OR^{PR}$, $-SR^{PR}$, $-N(R^{PR})_2$, an ester, a thioester, a phosphoester, a monosaccharide, an oligosaccharide, a carbonate or a carbamate and R^9 is $-CH_2-$ or $-CH=$;

(17) R^1 is $-OH$, R^2 is $-OH$ or $=O$, R^3 is $-H$, R^4 is $-OR^{PR}$, $-SR^{PR}$, $-N(R^{PR})_2$, an ester, a thioester, a phosphoester, a monosaccharide, an oligosaccharide, a carbonate or a carbamate and R^9 is $-CH_2-$ or $-CH=$;

20 (18) any of (1) through (17) above wherein R^9 is $-O-$ instead of $-CH_2-$ or $-CH=$; or

(19) any of (1) through (17) above wherein R^9 is $-NH-$ instead of $-CH_2-$ or $-CH=$.

25 Claim 26 (new): The method of claim 25 wherein the compound has the structure

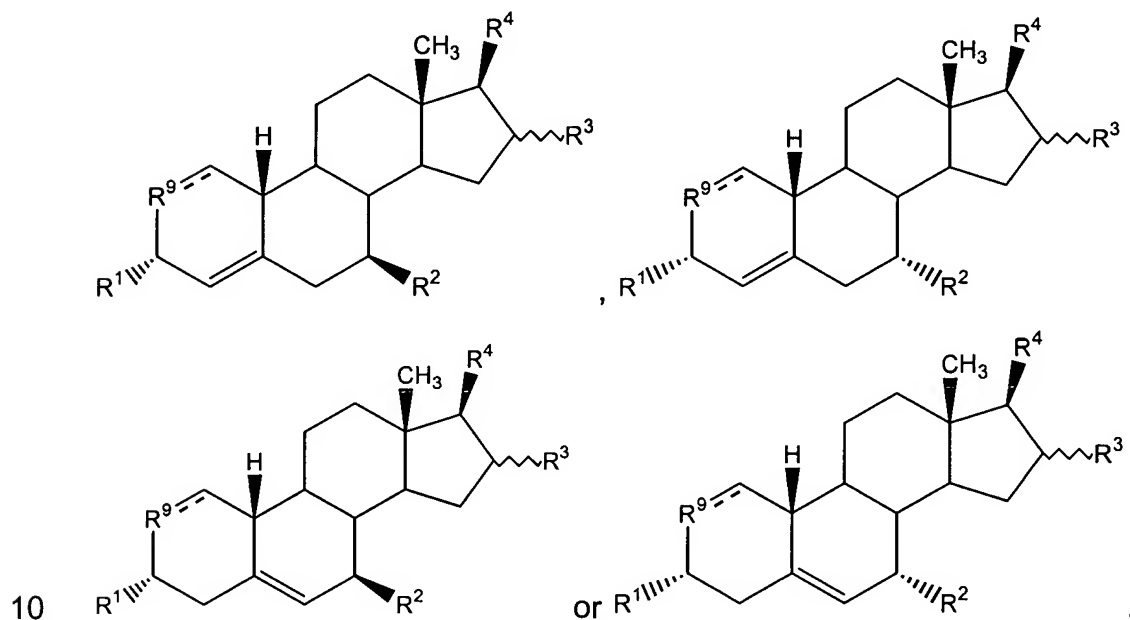


- Claim 27 (new): The method of claim 24 wherein the compound is
- 5 $3\alpha, 17\beta$ -dihydroxy-19-norandrost-4-ene, $3\alpha, 17\beta$ -dihydroxy-19-norandrost-5-ene, $3\alpha, 17\beta$ -dihydroxyandrost-4-ene, $3\alpha, 17\beta$ -dihydroxyandrost-5-ene, $3\alpha, 16\alpha, 17\beta$ -trihydroxy-19-norandrost-4-ene, $3\alpha, 16\alpha, 17\beta$ -trihydroxy-19-norandrost-5-ene, $3\alpha, 16\alpha, 17\beta$ -trihydroxyandrost-4-ene, $3\alpha, 16\alpha, 17\beta$ -trihydroxyandrost-5-ene, $3\alpha, 16\beta, 17\beta$ -trihydroxy-19-norandrost-4-ene, $3\alpha, 16\beta, 17\beta$ -trihydroxy-19-
 - 10 norandrost-5-ene, $3\alpha, 16\beta, 17\beta$ -trihydroxyandrost-4-ene, $3\alpha, 16\beta, 17\beta$ -trihydroxyandrost-5-ene, $3\alpha, 7\beta, 17\beta$ -trihydroxy-19-norandrost-4-ene, $3\alpha, 7\beta, 17\beta$ -trihydroxy-19-norandrost-5-ene, $3\alpha, 7\beta, 17\beta$ -trihydroxyandrost-4-ene, $3\alpha, 7\beta, 17\beta$ -trihydroxyandrost-5-ene, $3\alpha, 17\beta$ -dihydroxy-16 α -fluoro-19-norandrost-4-ene, $3\alpha, 17\beta$ -dihydroxy-16 α -fluoro-19-norandrost-5-ene, $3\alpha, 17\beta$ -dihydroxy-16 α -
 - 15 fluoroandrost-4-ene, $3\alpha, 17\beta$ -dihydroxy-16 α -fluoroandrost-5-ene, $3\alpha, 17\beta$ -dihydroxy-16 β -fluoro-19-norandrost-4-ene, $3\alpha, 17\beta$ -dihydroxy-16 β -fluoro-19-norandrost-5-ene, $3\alpha, 17\beta$ -dihydroxy-16 β -fluoroandrost-4-ene, $3\alpha, 17\beta$ -dihydroxy-16 β -fluoroandrost-5-ene, $3\alpha, 17\beta$ -dihydroxy-16 α -bromo-19-norandrost-4-ene, $3\alpha, 17\beta$ -dihydroxy-16 α -bromo-19-norandrost-5-ene, $3\alpha, 17\beta$ -dihydroxy-16 α -
 - 20 bromoandrost-4-ene or $3\alpha, 17\beta$ -dihydroxy-16 α -bromoandrost-5-ene, $3\alpha, 17\beta$ -

dihydroxy-16 β -bromo-19-norandrost-4-ene, 3 α ,17 β -dihydroxy-16 β -bromo-19-norandrost-5-ene, 3 α ,17 β -dihydroxy-16 β -bromoandrost-4-ene or 3 α ,17 β -dihydroxy-16 β -bromoandrost-5-ene.

- 5 Claim 28 (new): The method of claim 27 wherein the subject has osteoporosis and the compound is 3 α ,17 β -dihydroxy-19-norandrost-4-ene.

Claim 29 (new): A compound having the structure



wherein,

- R^1 is $-OR^{PR}$, $-SR^{PR}$, $-N(R^{PR})_2$, $-N_3$, an ester, a phosphoester, a phosphothioester, a sulfate ester, an amino acid, a peptide, an ether, a thioether, a carbonate, a carbamate, an optionally substituted
 15 monosaccharide or an optionally substituted oligosaccharide;
 R^2 and R^{10} independently are $-H$, $-OR^{PR}$, $-SR^{PR}$, $-N(R^{PR})_2$, $-N_3$, $-CN$, $-NO_2$, an ester, a thioester, a phosphoester, a phosphothioester, a phosphonoester, a phosphiniester, a sulfite ester, a sulfate ester, an amide, an amino acid, a peptide, an ether, a thioether, an acyl group, a thioacyl
 20 group, a carbonate, a carbamate, a thioacetal, a halogen, an optionally substituted alkyl group, an optionally substituted alkenyl group, an optionally

substituted alkynyl group, an optionally substituted aryl moiety, an optionally substituted heteroaryl moiety, an optionally substituted monosaccharide, an optionally substituted oligosaccharide, or,

R^3 is $-OR^{PR}$, $=O$, $-SR^{PR}$, $=S$, $-N(R^{PR})_2$, $-N_3$, $-NO_2$, an ester, a

5 phosphoester, a phosphothioester, a sulfate ester, an amino acid, a peptide, an ether, a thioether, a carbonate, a carbamate or a halogen;

R^4 is $-OR^{PR}$, $=O$, $-SR^{PR}$, $=S$, $-N(R^{PR})_2$, $-N_3$, $=NOH$, an ester, a

phosphoester, a phosphothioester, a sulfate ester, an amino acid, a peptide, an ether, a thioether, a carbonate, a carbamate, an optionally substituted

10 monosaccharide or an optionally substituted oligosaccharide;

R^6 is $-H$ or optionally substituted alkyl;

R^9 is $-CHR^{10}-$, $-O-$, $-S-$, $-NR^{PR}-$, or R^9 is absent, leaving a 5-membered ring;

R^{13} independently is C_{1-6} alkyl;

15 R^{PR} independently are $-H$ or a protecting group.

Claim 30 (new): The compound of claim 29 wherein the compound is

$3\alpha, 16\alpha, 17\beta$ -trihydroxy-19-norandrost-4-ene, $3\alpha, 16\alpha, 17\beta$ -trihydroxy-19-

norandrost-5-ene, $3\alpha, 16\alpha, 17\beta$ -trihydroxyandrost-4-ene, $3\alpha, 16\alpha, 17\beta$ -

20 trihydroxyandrost-5-ene, $3\alpha, 16\beta, 17\beta$ -trihydroxy-19-norandrost-4-ene,

$3\alpha, 16\beta, 17\beta$ -trihydroxy-19-norandrost-5-ene, $3\alpha, 16\beta, 17\beta$ -trihydroxyandrost-4-

ene, $3\alpha, 16\beta, 17\beta$ -trihydroxyandrost-5-ene, $3\alpha, 7\beta, 17\beta$ -trihydroxy-19-

norandrost-4-ene, $3\alpha, 7\beta, 17\beta$ -trihydroxy-19-norandrost-5-ene, $3\alpha, 7\beta, 17\beta$ -

trihydroxyandrost-4-ene, $3\alpha, 7\beta, 17\beta$ -trihydroxyandrost-5-ene, $3\alpha, 17\beta$ -

25 dihydroxy- 16α -fluoro-19-norandrost-4-ene, $3\alpha, 17\beta$ -dihydroxy- 16α -fluoro-19-

norandrost-5-ene, $3\alpha, 17\beta$ -dihydroxy- 16α -fluoroandrost-4-ene, $3\alpha, 17\beta$ -

dihydroxy- 16α -fluoroandrost-5-ene, $3\alpha, 17\beta$ -dihydroxy- 16β -fluoro-19-

norandrost-4-ene, $3\alpha, 17\beta$ -dihydroxy- 16β -fluoro-19-norandrost-5-ene, $3\alpha, 17\beta$ -

dihydroxy- 16β -fluoroandrost-4-ene, $3\alpha, 17\beta$ -dihydroxy- 16β -fluoroandrost-5-

30 ene, $3\alpha, 17\beta$ -dihydroxy- 16α -bromo-19-norandrost-4-ene, $3\alpha, 17\beta$ -dihydroxy-

16 α -bromo-19-norandrost-5-ene, 3 α ,17 β -dihydroxy-16 α -bromoandrost-4-ene
or 3 α ,17 β -dihydroxy-16 α -bromoandrost-5-ene, 3 α ,17 β -dihydroxy-16 β -bromo-
19-norandrost-4-ene, 3 α ,17 β -dihydroxy-16 β -bromo-19-norandrost-5-ene,
3 α ,17 β -dihydroxy-16 β -bromoandrost-4-ene or 3 α ,17 β -dihydroxy-16 β -
5 bromoandrost-5-ene.

Claim 31 (new): A pharmaceutical formulation comprising one or more
excipients and 3 α ,17 β -dihydroxy-19-norandrost-5-ene or a compound of claim
29.

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